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5	IN THE UNITED STATES DISTRICT COURT	
6	FOR THE NORTHERN DISTRICT OF CALIFORNIA	
7	FOR THE NORTHERN DISTRICT OF CALIFORNIA	
8	DD ADLEY C. DIDDING	
9	BRADLEY G. PIRRUNG, Individually and as Successor in Interest to CAROLE S. O'NEILL-PIRRUNG (DECEASED)) 3:19-cv-07575	
10	Plaintiff(s), COMPLAINT	
11	v.)	
12	JOHNSON & JOHNSON, and JOHNSON &) JURY TRIAL DEMANDED Output Description:	
14	JOHNSON CONSUMER INC., f/k/a) JOHNSON & JOHNSON CONSUMER)	
15	COMPANIES, INC.,	
16		
17	I. <u>COMPLAINT</u>	
18		
19	Plaintiff Bradley G. Pirrung, Individually and as Successor in Interest to Carole S.	
20	O'Neill-Pirrung (Deceased), by and through undersigned counsel, brings this action against	
21	Defendants Johnson & Johnson ("J&J") and be Johnson & Johnson Consumer Inc. f/k/a Johnson	1
22	& Johnson Consumer Companies, Inc. ("Johnson & Johnson Consumer Companies, Inc.") as	
23	follows:	
24	II. INTRODUCTION	
25	1. This action arises out of Decedent Carole S. O'Neill's diagnosis of ovarian cancer	r
26	and death from ovarian cancer which was directly and proximately caused by her regular and	
27	prolonged exposure to talcum powder contained in Defendants' Johnson & Johnson Baby	
28	Powder (hereinafter "J&J Baby Powder") and Shower to Shower. Plaintiff is Decedent's spouse)

and Successor in Interest to and sole beneficiary of Decedent's Estate (Exhibit A, Declaration of Bradley G. Pirrung and brings this cause of action against Defendants for claims arising from the direct and proximate result of Defendants' and/or their corporate predecessors' negligent, willful and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, advertising, marketing, distribution, labeling, and/or sale of the products known as J&J Baby Powder and Shower to Shower (hereinafter collectively referred to as "Products").

III. PARTIES

- 2. Decedent was born in 1952 and used J&J Baby Powder and Shower to Shower, the "Products," for nearly her entire life. As a direct and proximate result of using the Products, Decedent was diagnosed with ovarian cancer by pathology following her exploratory laparotomy, total abdominal hysterectomy, bilateral salpingo-oophorectomy, and lymph node sampling. Decedent expired from ovarian cancer. Decedent resided at 405 Encinosa Court Windsor, California 95492 at the time of her diagnosis and death.
- 3. Defendant, Johnson & Johnson ("J&J"), is a New Jersey Corporation with its principal place of business in the State of New Jersey.
- 4. At all pertinent times, Johnson & Johnson was engaged in the business of manufacturing, marketing, testing, promoting, advertising, selling, and/or distributing the Products. At all pertinent times, Johnson & Johnson regularly transacted, solicited, and conducted business in all States of the United States, including the State of California.
- 5. Defendant, Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc. ("Johnson & Johnson Consumer Companies, Inc.") is a New Jersey corporation with its principal place of business in the State of New Jersey.
- 6. At all pertinent times, Johnson & Johnson Consumer Companies, Inc. was engaged in the business of manufacturing, marketing, testing, promoting, advertising, selling, and/or distributing the Products. At all pertinent times, Johnson & Johnson regularly transacted, solicited, and conducted business in all States of the United States, including the State of California.

7. At all pertinent times, all Defendants were engaged in the research, development, manufacture, design, testing, sale, advertising, and marketing of the Products, and introduced such products into interstate commerce with knowledge and intent that such products be sold in the State of California.

IV. JURISDITION AND VENUE

- 8. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d) because complete diversity exists between Plaintiff and Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum of value of \$75,000.
- Decedent, prior to and at the time of Decedent's death, was a citizen of the State of California.
- 10. Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc. prior to and at the time of commencement of this action and continuing to the present were and are corporate citizens of the State of New Jersey with their principal places of business in the State of New Jersey.
- 11. Complete diversity existed at the time of commencement of this action and continues to exist between the Plaintiff and all Defendants.
- 12. This Court has personal jurisdiction over Defendants because Defendants are authorized to conduct and do conduct business in the State of California. Defendants have marketed, promoted, distributed, advertised, and sold the Products in the State of California and Defendants have sufficient minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through their promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.
- 13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants transact substantial business in this District.

V. FACTS COMMON TO ALL COUNTS

- A. Background: Talc as a Carcinogen and Defendant's Knowledge
- 14. Talc is a magnesium trisilicate and is mined from the earth. Talc is an inorganic mineral.
- 15. Talc is the main substance in talcum powders. The Johnson & Johnson Defendants manufactured the Products. The Products are composed almost entirely of talc.
- 16. At all pertinent times, a feasible alternative to the Products has existed. For example, cornstarch is an organic carbohydrate that is quickly broken down by the body with no known health effects. Cornstarch powders have been sold and marketed for the same uses as the Products with nearly the same effectiveness.
- 17. Historically, "Johnson's Baby Powder" has been promoted as a symbol of freshness, cleanliness, and purity. During the time in question, the Johnson & Johnson Defendants advertised and marketed this product as the beacon of "freshness" and "comfort", eliminating friction on the skin, absorbing "excess wetness" helping keep skin feeling dry and comfortable, and "clinically proven gentle and mild." The Johnson & Johnson Defendants instructed women through advertisements to dust themselves with this product to mask odors. The bottle of "Johnson's Baby Powder" specifically targets women by stating, "For you, use every day to help feel soft, fresh, and comfortable."
- 18. During the time in question, the Johnson & Johnson Defendants advertised and marketed the product "Shower to Shower" as safe for use by women as evidenced in its slogan "A sprinkle a day keeps odor away", and through advertisements such as "Your body perspires in more places than just under your arms. Use SHOWER to SHOWER to feel dry, fresh and comfortable throughout the day." And "SHOWER to SHOWER can be used all over your body."
- 19. In 1971, the first study was conducted that suggested an association between talc and ovarian cancer. This study was conducted by Dr. W.J. Henderson and others in Cardiff, Wales.
- 20. In 1982, the first epidemiologic study was performed on talc powder use in the female genital area. This study was conducted by Dr. Daniel Cramer and others. This study

found a 92% increased risk in ovarian cancer with women who reported genital talc use. Shortly after this study was published, Dr. Bruce Semple of Johnson & Johnson came and visited Dr. Cramer about his study. Dr. Cramer advised Dr. Semple that Johnson & Johnson should place a warning on its talcum powders about the ovarian cancer risks so that women can make an informed decision about their health.

- 21. Since 1982, there have been approximately twenty-two (22) additional epidemiologic studies providing data regarding the association of talc and ovarian cancer. Nearly all of these studies have reported an elevated risk for ovarian cancer associated with genital talc use in women.
- a. In 1983, a case-control study found a 150% increased risk of ovarian cancer for women who use talcum powder in the genital area. Hartge, P., et al. Talc and Ovarian Cancer. *JAMA*. 1983; 250(14):1844.
- b. In 1988, a case control study of 188 women diagnosed with epithelial ovarian cancer and 539 control women found that 52% of the cancer patients habitually used talcum powder on the genital area before their cancer diagnosis. The study showed a 50% increase in risk of ovarian cancer in women that used talcum powder on their genital area and a positive dose-response relationship. Whittemore AS, *et al.* Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee. *Am.J. Epidemiol.* 1988 Dec; 128(6):1228-40.
- c. A 1989 study looked at 235 women diagnosed with epithelial ovarian cancer and 451 controls, and found a 29% increased risk in ovarian cancer with women who reported genital talcum powder use more than once each week. Booth, M., *et al.* Risk factors for ovarian cancer: a case-control study. *Br J Cancer*. 1989 Oct; 60(4):592-8.
- d. In 1992, a case-control study found a statistically significant 80% increased risk of ovarian cancer in women with more than 10,000 lifetime perineal applications of talc, demonstrating a positive dose-response relationship. Harlow BL, *et al.* Perineal exposure to talc and ovarian cancer risk. *Obstet Gynecol.* 1992 Jul; 80(1):19-26.

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- e. Another 1992 case-control study reported a 70% increased risk from genital talc use and a 379% increased risk of ovarian cancer of women who used talc on sanitary napkins in their genital area. Rosenblatt, K.A. *et al.* Mineral fiber exposure and the development of ovarian cancer. *Gynecol Oncol.* 1992 Apr; 45(1):20-5.
- f. In 1995, the largest study of its kind to date found a statistically significant 27% increased risk in ovarian cancer for women who regularly use talc in the abdominal or perineal area. Purdie, D., et al. Reproductive and other factors and risk of epithelial ovarian cancer: An Australian case-control study. Survey of Women's Health Study Group. Int J Cancer. 1995 Sep 15; 62(6):678-84.
- g. In 1996, a case-control study found a statistically significant 97% increased risk of ovarian cancer in women who used what they described as a "moderate" or higher use of talc-based powders in their genital area. See Shushan, A., et al. Human menopausal gonadotropin and the risk of epithelial ovarian cancer. Fertil. Steril. 1996 Jan; 65(1):13-8.
- h. In 1997, a case control study of 313 women with ovarian cancer and 422 without this disease found that the women with cancer were more likely to have applied talcum powder to their external genitalia area. Women using these products had a statistically significant 50% to 90% higher risk of developing ovarian cancer. Cook, LS, *et al.* Perineal powder exposure and the risk of ovarian cancer. *Am. J Epidemiol.* 1997 Mar 1; 145(5):459-65.
- i. In 1997, a case-control study involving over 1,000 women found a statistically significant increased risk of 42% for ovarian cancer for women who applied talc via sanitary napkins to their perineal area. Chang. S, et al. Perineal talc exposure and risk of ovarian carcinoma. Cancer. 1997 Jun 15; 79(12):2396-401.
- j. In 1998, a case-control study found a 149% increased risk of ovarian cancer in women who used talc-based powders on their perineal area. Godard, B., *et al.* Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study. *Am J Obstet Gynecol.* 1998 Aug; 179(2):403-10.

- k. Dr. Daniel Cramer conducted another case-control study in 1999, observing 563 women newly diagnosed with epithelial ovarian cancer and 523 women in a control. The study found a statistically significant 60% increased risk of ovarian cancer in women that used talc-based body powders on their perineal area and an 80% increase in risk for women with over 10,000 lifetime applications. Cramer, DW, et al. Genital talc exposure and risk of ovarian cancer. Int J Cancer. 1999 May 5; 81(3):351-56.
- 1. In 2000, a case-control study of over 2,000 women found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. Ness, RB, et al. Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer.

 Epidemiology. 2000 Mar; 11(2):111-7.
- m. In 2004, a case-control study of nearly, 1,400 women from 22 counties in Central California found a statistically significant 37% increased risk of epithelial ovarian cancer from women's genital talc use, and a 77% increased risk of serous invasive ovarian cancer from women's genital talc use. Importantly, this study also examined at women's use of cornstarch powders as an alternative to talc, and found no increased risk in ovarian cancer in women in the cornstarch group, further supporting the causal connection between genital talc use and ovarian cancer. Mills, PK, et al. Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *Int J Cancer*. 2004 Nov 10; 112(3):458-64.
- n. In 2008, a combined study of over 3,000 women from a New England-based case-control study found a general 36% statistically significant increased risk of epithelial ovarian cancer from genital talc use and a 60% increased risk of the serous invasive ovarian cancer subtype. The study also found a strong dose-response relationship between the cumulative talc exposure and incidence of ovarian cancer, adding further support to the causal relationship. Gates, MA, *et al.* Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer. *Cancer Epidemiol Biomarkers Prev.* 2008 Sep; 17(9):2436-44
- o. A 2009 case-control study of over 1,200 women found the risk of ovarian cancer increased significantly with increasing frequency and duration of talc use, with an overall

 statistically significant 53% increased risk of ovarian cancer from genital talc use. That increased risk rose dramatically, to 108%, in women with the longest duration and most frequent talc use. Wu, AH, et al. Markers of inflammation and risk of ovarian cancer in Los Angeles County. Int. J Cancer. 2009 Mar 15; 124(6):1409-15.

- p. In 2011, another case-control study of over 2,000 women found a 27% increased risk of ovarian cancer from genital talc use. Rosenblatt, KA, *et al.* Genital powder exposure and the risk epithelial ovarian cancer. *Cancer Causes Control*. 2011 May; 22(5):737-742.
- q. In June of 2013, a pooled analysis of over 18,000 women in eight case-control studies found a 20% to 30% increased risk of women developing epithelial ovarian cancer from genital powder use. The study concluded by stating, "Because there are few modifiable risk factors for ovarian cancer, avoidance of genital powders may be a possible strategy to reduce ovarian cancer incidence." Terry, KL, *et al.* Genital powder use and risk of ovarian cancer: a pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prev Res (Phila)*. 2013 Aug; 6(8):811-21.
- 22. Researchers have also examined the link between endometrial cancer, a form of uterine cancer, and application of talcum powder to the perineal area.
- 23. In 2010, one such study analyzed data from a 1976 cohort study of over 66,000 women, and found a statistically significant 21% increased risk of endometrial (uterine) cancer in postmenopausal women who had ever applied talcum powder in the perineal area. This risk rose to 24% for postmenopausal women who applied talc in the perineal area "regularly," defined as at least once a week. Karageorgi S., *et al.* (2010) Perineal use of talcum powder and endometrial cancer risk. *Cancer Epidemiol Biomarkers Prev.* 2010 May; 19:1269-1275.
- 24. In 1993, the United States National Toxicology Program published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity. Talc was found to be a carcinogen, with or without the presence of asbestos-like fibers.
- 25. In response to the United States National Toxicology Program's study, the Cosmetic Toiletry and Fragrance Association (CTFA) formed the Talc Interested Party Task

Force (TIPTF). Johnson & Johnson, Inc., and Johnson & Johnson Consumer Companies, Inc. were members of the CFTA. The stated purpose of the TIPTF was to pool financial resources of these companies in an effort to collectively defend talc use at all costs and to prevent regulation of any type over this industry. The TIPTF hired scientists to perform biased research regarding the safety of talc, members of the TIPTF edited scientific reports of the scientists hired by this group prior to the submission of these scientific reports to governmental agencies, members of the TIPTF knowingly released false information about the safety of talc to the consuming public, and used political and economic influence on regulatory bodies regarding talc. All of these activities have been well coordinated and planned by these companies and organizations over the past four (4) decades in an effort to prevent regulation of talc and to create confusion to the consuming public about the true hazards of talc relative to cancer.

- 26. On November 10, 1994, the Cancer Prevention Coalition mailed a letter to then Johnson & Johnson C.E.O, Ralph Larson, informing his company that studies as far back as 1960's "... show[] conclusively that the frequent use of talcum powder in the genital area pose[] a serious health risk of ovarian cancer." The letter cited a recent study by Dr. Bernard Harlow from Harvard Medical School confirming this fact and quoted a portion of the study where Dr. Harlow and his colleagues discouraged the use of talc in the female genital area. The letter further stated that 14,000 women per year die from ovarian cancer and that this type of cancer is very difficult to detect and has a low survival rate. The letter concluded by requesting that Johnson & Johnson withdraw talc products from the market because of the alternative of cornstarch powders, or at a minimum, place warning information on its talc-based boy powders about ovarian cancer risk they pose.
- 27. In 1996, the condom industry stopped dusting condoms with talc due to the growing health concerns.
- 28. In February of 2006, the International Association for the Research of Cancer (IARC) part of the World Health Organization published a paper whereby they classified perineal use of talc based body powder as a "Group 2B" human carcinogen. IARC which is universally accepted as the international authority on cancer issues, concluded that studies from

around the world consistently found an increased risk of ovarian cancer in women from perineal

use of talc. IARC found that between 16-52% if women in the world were using talc to dust their perineum and found an increased risk of ovarian cancer in women talc users ranging from 30-60%. IARC concluded with this "Evaluation": "There is limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder." By definition "Limited evidence of carcinogenicity" means "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."

29. In approximately 2006, the Canadian government under The Hazardous Products

- 29. In approximately 2006, the Canadian government under The Hazardous Products Act and associated Controlled Products Regulations classified talc as a "D2A," "very toxic," 51 "cancer causing" substance under its Workplace Hazardous Materials Information System (WHMIS). Asbestos is also classified as "D2A".
- 30. In 2006, Imerys Talc began placing a warning on the Material Safety Data Sheets (MSDS) it provided to the Johnson & Johnson Defendants regarding the talc it sold to them to be used in the Products. These MSDSs not only provided the warning information about the IARC classification but also included warning information regarding "States Rights to Know" and warning information about the Canadian Government's "D2A" classification of talc as well.
- 31. Defendants had a duty to know and warn about the hazards associated with the use of the Products.
- 32. Defendants failed to inform customers and end users including the Decedent of the Products known catastrophic health hazard associated with the use of the Products.
- 33. In addition, Defendants procured and disseminated false, misleading, and biased information regarding the safety of the Products to the public, including the Decedent, and used influence over governmental and regulatory bodies regarding talc.
 - B. Decedent's Use of the Products
 - 34. Decedent was born in 1952 and was a resident of Windsor, California.

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- 35. When Decedent was an infant, her mother applied Shower to Shower, and J&J Baby Powder to Decedent. As she grew up, and throughout her life, Decedent continued to use the Products daily.
- 36. Decedent continued to use the Products following her initial diagnosis of ovarian cancer.
- 37. There was never any indication, on the Products, packaging or otherwise, that this normal use could and would cause Decedent to have developed or to develop ovarian cancer.
 - 38. Decedent was diagnosed with ovarian cancer.
- 39. Decedent underwent chemotherapy and surgery including her exploratory laparotomy, total abdominal hysterectomy, bilateral salpingo-oophorectomy, and lymph node sampling.
 - 40. Decedent's ovarian cancer was the cause of her death on April 25, 2014.

COUNT ONE-STRICT LIABILITY

(FAILURE TO WARN)

- 41. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 42. At all pertinent times, the Johnson & Johnson Defendants were manufacturing, marketing, testing, promoting, selling and/or distributing the Products in the regular course of business.
- 43. At all pertinent times, Decedent used the Products to powder her perineal area, which is a reasonably foreseeable use.
- 44. At all pertinent times, Defendants in this action knew or should have known that the use of talcum powder based products in the perineal area significantly increases the risk of cancer, including, but not limited to, ovarian and uterine cancer, based upon scientific knowledge dating back decades.
- 45. At all pertinent times, including the time of sale and consumption, the Products, when put to the aforementioned reasonably foreseeable use, were in an unreasonably dangerous and defective condition because they failed to contain adequate and proper warnings and/or

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instructions regarding the increased risk of cancer, including, but not limited to, ovarian and uterine cancer, associated with the use of the Products by women to powder their perineal area. Defendants themselves failed to properly and adequately warn and instruct Decedent as to the risks and benefits of the Products given her need for this information.

- 46. Had Decedent been given warning that the use of the Products would significantly increase her risk of developing cancer, she would not have used them. As a proximate result of Defendants' design, manufacturing, marketing, sale, and distribution of the Products, Decedent was injured catastrophically, and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, economic damages, and death.
- 47. The development of ovarian cancer by Decedent and Decedent's death were the direct and proximate results of the unreasonably dangerous and defective condition of the Products at the time of sale and consumption, including their lack of warnings; Decedent suffered injuries and damages including, but not limited to, physical and mental pain and suffering, fear of death, medical expenses, funeral and burial expenses and death.
- 48. Defendants' products were defective because they failed to contain warnings and/or instructions, and breached express warranties and/or failed to conform to express factual representations upon which Decedent justifiably relied in electing to use the Products. The defect or defects made the Products unreasonably dangerous to persons, such as Decedent, who could reasonably be expected to use and rely upon such products. As a result, the defect or defects were a producing cause of Decedent's injuries, damages, and death.
- 49. Defendants' products failed to contain, and still today do not to contain, adequate warnings and/or instructions regarding the increased risk of cancer, including, but not limited to, ovarian and uterine cancer, with the use of their products by women. Defendants continue to market, advertise, and expressly represent to the general public that it is safe for women to use their products regardless of application. The Defendants continue with these marketing and advertising campaigns despite having scientific knowledge that dates back to the 1960's that their products increase the risk of cancer in women when used in the perineal area.

- 50. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:
- a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT TWO – STRICT LIABILITY

(DESIGN AND/OR MANUFACTURING DEFECT)

- 51. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 52. Defendants engaged in the design, development, manufacturing, marketing, sale, and distribution of the Products in a defective and unreasonably dangerous condition to consumers, including Decedent.
- 53. Defendants caused the Products to enter the stream of commerce and to be sold through various retailers, where Decedent purchased the Products.
- 54. The Products were expected to, and did, reach consumers, including Decedent, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.
- 55. Decedent used the Products in a manner normally intended, recommended, promoted, and marketed by Defendants.
- 56. Products failed to perform safely when used by Decedent in a reasonably foreseeable manner, specifically increasing Decedent's risk of developing ovarian cancer.
- 57. The propensity of talc fibers to translocate into the female reproductive system, including, but not limited to, the ovaries and endometrial lining of the uterus, thereby substantially increasing risk of cancer, including, but not limited to, ovarian and uterine cancer, renders the Products unreasonably dangerous when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer, including the Decedent.

- 58. Importantly, the Products are inessential cosmetic products that do not treat or cure any serious disease. Further, safer alternatives, including corn-starch based powders, have been readily available for decades.
- 59. Defendants have known, or should have known, that the Products are unreasonably dangerous when used by a woman in her perineal area but have continued to design, manufacture, sell, distribute, market, promote, and supply the Products so as to maximize sales and profits at the expense of public health and safety in conscious disregard of the foreseeable harm to the consuming public, including Decedent.
- 60. As a direct and proximate result of Defendants' conduct, including actions, omissions, and misrepresentations, Decedent sustained the following damages:
- a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT THREE-NEGLIENCE

- 61. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 62. The Johnson & Johnson Defendants were negligent in marketing, designing, manufacturing, producing, supplying, inspecting, testing, advertising selling and/or distributing the Products in one or more of the following respects:
 - In failing to warn Decedent and the general public of the hazards associated with the use of Products;
 - In failing to properly test their products to determine adequacy and effectiveness of safety measures, if any, prior to releasing the Products for consumer use;
 - In failing to properly test their products to determine the increased risk of ovarian cancer during the normal and/or intended use of the Products;

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- In failing to inform ultimate users, including the Decedent, as to the safe and proper methods of handling and using the Products;
- In failing to remove the Products from the market when Defendants knew or should have known the Products were defective;
- In failing to instruct the ultimate users, including the Decedent, as to the methods
 for reducing the type of exposure to the Products which caused increased risk of
 cancer, including, but not limited to, ovarian and uterine cancer;
- In failing to inform the public in general and Decedent in particular of the known dangers of using the Products for dusting the perineum;
- In failing to advise users including the Decedent how to prevent or reduce exposure that causes increased risk for cancer, including, but not limited to, ovarian and uterine cancer;
- In marketing and labeling the Products as safe for all uses despite knowledge to the contrary; and
- In failing to act like a reasonably prudent company under similar circumstances.

Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by Decedent.

- 63. At all pertinent times, the Johnson & Johnson Defendants knew or should have known that the Products were unreasonably dangerous and defective when put to their reasonably anticipated use.
- 64. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:
- a. Economic losses including medical expenses, lost earnings, funeral, burial and related expenses.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, and loss of enjoyment and impairment of quality of life, and death.

COUNT FOUR-BREACH OF EXPRESS WARRANTY

- 65. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 66. The Johnson & Johnson Defendants expressly warranted, through direct-to-consumer marketing, advertisements, and labels, including to the Decedent that the Products were safe and effective for reasonably anticipated uses, including use by women in the perineal area.
- 67. The Products did not conform to these express representations because they cause serious injury when used by women in the perineal area in the form of cancer, including, but no limited to, ovarian and uterine cancer.
- 68. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:
- a. Economic losses including medical expenses, lost earnings, funeral, burial and related expenses.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT FIVE - BREACH OF IMPLIED WARRANTIES

- 69. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 70. At the time the Defendants manufactured, marketed, labeled, promoted, distributed and/or sold the Products, the Johnson & Johnson Defendants knew of the uses for which the Products were intended, including use by women in the perineal area, and impliedly warranted the Products to be of merchantable quality and safe for such use.
- 71. Defendants breached their implied warranties of the Products sold to Decedent because they were not fit for their common, ordinary and intended uses, including use by women in the perineal area.

- 72. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:
- a. Economic losses including medical expenses, lost earnings, funeral, burial and related expenses.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT SIX – PUNITIVE DAMAGES

- 73. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 74. Defendants have acted willfully, wantonly, with an evil motive, and recklessly in one or more of the following ways:
 - a. Defendants knew of the unreasonably high risk of cancer, including, but not limited to, ovarian and uterine cancer, posed by the Products before manufacturing, marketing, distributing and/or selling the Products, yet purposefully proceeded with such action;
 - Despite their knowledge of the high risk of cancer, including, but not limited to,
 ovarian and uterine cancer, associated with the Products, Defendants affirmatively
 minimized this risk through marketing and promotional efforts and product
 labeling;
 - c. Through the actions outlined above, Defendants expressed a reckless indifference to the safety of users of the Products, including Decedent. Defendants' conduct, as described herein, knowing the dangers and risks of the Products, yet concealing and/or omitting this information, in furtherance of their conspiracy and concerted action was outrageous because of Defendants' evil motive or reckless indifference to the safety of users of the Products.
- 75. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and /or omissions:

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- Economic losses including medical care, lost earnings, funeral, burial and a. related expenses.
- Noneconomic losses including physical and mental pain and suffering, b. emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT SEVEN – NEGLIGENT MISREPRESENTATION

- 76. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 77. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Decedent, and the public, that the Products had been tested and found to be safe and effective for use in the perineal area. The representations made by Defendants, in fact, were false.
- 78. Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Products' high risk of unreasonable, dangerous, adverse side effects.
- 79. Defendants breached their duty in representing that the Products have no serious side effects.
- 80. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, but not limited to, ovarian and uterine cancer.
- 81. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:
- a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering,
 emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT EIGHT - FRAUDULENT CONCEALMENT

- 82. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 83. Defendants owed consumers, including Decedent, a duty to fully and accurately disclose all materials facts regarding the Products, not to conceal material defects related thereto, not to place these defective products into the stream of commerce, and to fully and accurately label product packaging. To the contrary, Defendants explicitly and/or implicitly represented that the Products were safe and effective.
- 84. Defendants actively and intentionally concealed and/or suppressed material facts, in whole or in part, to induce consumers, including Decedent, to purchase and use the Products and did so at her expense. Specifically:
- a. Defendants have been aware of the positive association between feminine talc use and cancer demonstrated by epidemiological studies since at least 1982 and more than a dozen such published studies, including meta-analyses, have since been published demonstrating similar results;
- b. Defendants have been aware, for decades, of the propensity for talc particles to translocate from the perineum through the vaginal tract into the ovaries;
- c. IARC, the recognized world authority of agent carcinogenicity, has determined that there is causal relationship between feminine talc use and ovarian cancer;
- d. Johnson & Johnson's own paid consultant, Dr. Alfred Wehner, advised the company on multiple occasions, by at least 1997, that Johnson & Johnson's denial of a positive association between feminine talc use and ovarian cancer was "technically and factually incorrect."; and
- e. Recent studies have again confirmed a statistically significant correlation between talcum powder use in the perineal area and uterine cancer.

85.

deceiving and defrauding Decedent and with the intention of having her act and rely on such misrepresentations and/or omissions.

86. Defendants knew that their concealments, misrepresentations and/or omissions.

Defendants made the misrepresentation and/or omissions for the purpose of

- 86. Defendants knew that their concealments, misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive, and deceitful when they were made. Alternatively, Defendants concealed information, and/or made the representations with such reckless disregard for the truth that knowledge of the falsity can be imputed to them.
- 87. Defendants profited, significantly, from their unethical and illegal conduct that caused Decedent to purchase and habitually use a dangerous and defective product.
- 88. Defendants' actions, and Decedent's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.
- 89. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:
- a. Economic losses including medical expenses, lost earnings, funeral, burial and related expenses.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT NINE – FRAUD

(INTENTIONAL MISREPRESENTATION)

- 90. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 91. Defendants, who engaged in the development, manufacture, marketing, sale and distribution of personal hygiene products, including the Products, owed a duty to provide accurate and complete information regarding said products.
- 92. Defendants fraudulently misrepresented the use of the Products as safe and effective, including to Decedent, specifically:

- a. Johnson & Johnson's website calls it a "misconception" that talc is baby powder that can be "absorbed into the body";
- b. Johnson & Johnson print advertisements directed at adult women asserting that, because Johnson & Johnson Baby Powder is used on babies, women can "trust" that Johnson & Johnson will take "just as much care" of their skin:
- c. Misleading consumers in advertisements that the talc in Johnson & Johnson Baby Powder is safe because it comes from "nature" and is "pure";
- d. Johnson & Johnson, on its website, claims that "30 years of research by independent scientists, review boards and global authorities have concluded that talc can be used safely in personal care products," failing to mention the dozens of studies demonstrating a relationship between feminine talc use and ovarian cancer, as well as the decision by IARC to label feminine talc powder use as "possibly carcinogenic"; and
- e. On the Johnson & Johnson Baby Powder bottle, Defendants include a conspicuous warning to mothers to prevent babies from inhaling the powder, and the inclusion of this lone warning implies to the consumers that Johnson & Johnson Baby Powder is safe in all other manners of use.
- 93. Defendants knew that these misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive and deceitful when they were made.
- 94. Defendants made the misrepresentations and/or omissions for the purpose of deceiving and defrauding consumers, including Decedent, with the intention of having them act and rely on such misrepresentations and/or omissions.
- 95. Decedent relied, with reasonable justification, on the misrepresentations by Defendants, which induced her to purchase and use the Products on a regular basis for decades.
- 96. Defendants profited significantly from their unethical and illegal conduct that fraudulently induced Decedent, and millions of other consumers, to purchase a dangerous and defective product.
- 97. Defendants' actions, and Decedent's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

- 98. As a foreseeable, direct, and proximate result of the aforementioned fraudulent misrepresentations by Defendants, Decedent sustained the following damages:
 - a. Economic losses including medical expenses and lost earnings.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT TEN - VIOLATION OF THE UCL

- 99. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 100. California's UCL prohibits any "unlawful, unfair, or fraudulent" business practice. Cal. Bus. & Prof. Code § 17200. Defendants' misrepresentations and omissions described herein are "unlawful, unfair and fraudulent" under California law.
- 101. Decedent purchased and used the Johnson & Johnson Defendants' Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the UCL.
- 102. Had Defendants not engaged in the deceptive conduct described herein, Decedent would not have purchased and/or paid for Defendants' Products, and would not have incurred related injuries and damages.
- 103. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monetary gain from Decedent for the Products that would not have been paid had Defendants not engaged in fraudulent conduct.
- 104. Defendants engaged in fraudulent methods of competition and deceptive acts or practices that were proscribed by law, including the following:
- a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;
- b. Advertising goods or services with the intent not to sell them as advertised; and

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- c. Engaging in fraudulent conduct that creates a likelihood of confusion or misunderstanding.
- 105. Defendants intended for the public, including Decedent, to rely on their representations and advertisements regarding the Products in order to achieve monetary gain from Decedent through their purchase of Products.
- 106. Decedent was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at Decedent and other consumers was to create demand for and sell the Products. Each aspect of Defendants' conduct combined to create sales of the Products.
- 107. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacturing, promotion, and sale of the Products.
- 108. Had Defendants not engaged in the deceptive conduct described above, Decedent would not have purchased and/or paid for the product, and would not have incurred related injuries and damages.
- 109. Defendants' intentional, deceptive, unconscionable, and fraudulent representations and material omissions to the public, Decedent, physicians, and consumers, constituted unfair and deceptive acts and trade practices in violation of Cal. Bus. & Prof. Code. § 17200.
- 110. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of Cal. Bus. & Prof. Code. § 17200.
- 111. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices, or have made false representations in violation of Cal. Bus. & Prof. Code. § 17200.
- 112. Defendants are the suppliers, manufacturers, advertisers, and sellers of the Products, and are subject to liability under Cal. Bus. & Prof. Code. § 17200 for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

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- 113. Defendants violated Cal. Bus. & Prof. Code. § 17200, by knowingly and falsely representing that Defendants' Products were fit to be used for the purpose for which they were intended, when in fact the Products were and are defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.
- 114. Defendants had actual knowledge of the defective and dangerous condition of Defendants' Products, and failed to take any action to cure such defective and dangerous conditions.
- 115. Decedent reasonably relied upon Defendants' misrepresentations and omissions in determining which Products to use.
- 116. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to Decedent and other consumers constituted deceptive acts and practices.
- 117. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Decedent suffered ascertainable losses and damages.
- 118. As a direct and proximate result of Defendants' violations of Cal. Bus. & Prof.Code. § 17200, Decedent sustained the following damages:
- a. Economic losses including medical expenses, lost earnings, funeral, burial and related expenses.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment and impairment of quality of life, and death.

COUNT ELEVEN – RESTITUTION OR DISGORGMENT BASED ON UNJUST ENRICHMENT

- 119. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 120. As a result of the Johnson & Johnson Defendants' unlawful, fraudulent and misleading labeling, advertising, marketing and sales of the Products described herein, Defendants were unjustly enriched at the expense of Decedent.

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121. Defendants sold their Products to Decedent as described herein, and profited therefrom. It would be against equity and good conscience to permit Defendants to retain the ill-gotten benefits Defendants received from Decedent, in light of the fact that the Products were not what Defendants purported them to be. Thus, it would be unjust and inequitable for Defendants to retain the benefit without restitution or disgorgement to Decedent of monies paid to Defendants for the Products.

COUNT TWELVE - CONSUMER LEGAL REMEDIES ACT

- 122. Plaintiff incorporates by reference each of the preceding paragraphs as it fully set forth herein.
- 123. This cause of action is brought under the Consumer Legal Remedies Act, California Civil Code §§ 1750, et seq.
- 124. Plaintiff presently seeks only injunctive relief under this cause of action. Plaintiff will amend this cause of action to seek damages after giving the notice required by Cal. Civ. Code § 1782.
 - 125. Decedent was a "consumer" within the meaning of Civil Code § 1761(d).
- 126. Defendants' sales of their Products constitute "transactions" within the meaning of Civil Code § 1761(e). The Products purchased by Decedent constitute "goods" under Civil Code § 1761(a).
- 127. As described above, Defendants' representations to Decedent were false, in violation of the CLRA. Defendants' conduct violated, among others (1) Civil Code § 1770(a)(5), which prohibits "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have"; (2) Civil Code § 1770(a)(7), which prohibits "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another"; and (3) Civil Code § 1770(a)(9), which prohibits "[a]dvertising goods or services with intent not to sell them as advertised."

- 128. The violations of the CLRA by Defendants were willful, oppressive, and fraudulent.
- 129. Pursuant to Cal. Civ. Code § 1782(a)(2), Plaintiff is the Successor in Interest and sole beneficiary of Decedent's Estate and is entitled to an order enjoining the above-described acts and practices.

COUNT THIRTEEN – FALSE ADVERTISING LAW

- 130. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 131. This cause of action is brought under California's False Advertising Law, California Business & Professions Code §§ 17500, et seq.
- 132. The FAL prohibits the dissemination of any advertising which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading. Cal. Bus. & Prof. Code § 17500.
- 133. The Johnson & Johnson Defendants engaged in a scheme of offering the Products described herein for sale to the public and to Decedent by way of advertising, product packaging and labeling, and other promotional materials. Defendants misrepresented the true contents and nature of Defendants' Products to the public and the Decedent.
- 134. As explained herein, Defendants advertised, and continue to advertise, its Products in a manner that was, and is, untrue and misleading.
- 135. Defendants knew or should have known that their advertisements were and are misleading or likely to mislead for the reasons set forth above.
- 136. Defendants' advertisements and inducements were made within California and come within the definition of advertising as contained in Business and Professions Code § 17500, et seq.
- 137. Defendants' Product packaging and labeling, and promotional materials, were intended as inducements to purchase Defendants' Products, and are statements disseminated by Defendants to Decedent.

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III

- 138. Defendants' advertisements induced the public and Decedent to purchase Defendants' Products, as described herein.
- 139. The Plaintiff and Decedent suffered injuries in fact and losses of money or property as a result of Defendants' acts and practices, which violate §§ 17500, et seq.

COUNT FOURTEEN - WRONGFUL DEATH

- 140. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 141. Plaintiff is entitled to recover economic and noneconomic damages against

 Defendants for Decedent's wrongful death directly and legally caused by their conduct described herein.
- 142. Plaintiff was deprived of Decedent's love, companionship, comfort, support, affection, society, solace and moral support by Defendants' actions.
- 143. Said actions were conducted in conscious and malicious disregard for the right of Decedent. Said disregard resulted in injuries, special damages, and wrongful death and warrants recovery of punitive damages by Plaintiff against Defendants.

COUNT FIFTEEN – SURVIVAL ACTION

- 144. Plaintiff hereby incorporates by reference each of the preceding paragraph as if fully set forth herein.
- 145. Plaintiff incurred special damages in the form of reasonable value of services rendered for medical care for the injuries that Decedent sustained prior to her death caused by the Defendants' actions. A cause of action for recovery of such damages by Plaintiff survives death pursuant to California Code of Civil Procedure 377.
- 146. Defendants acted in conscious disregard for the safety of Decedent with respect to matters alleged herein. Said disregard resulted in injuries and special damages, and warrants recovery of punitive damages by Plaintiff against Defendants. Aforementioned damages survive Plaintiff's Decedent's death pursuant to California Code of Civil Procedure 3294 and 377.

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- 147. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 148. As a direct and proximate result of Defendant's conduct, as detailed above, Plaintiff Bradley G. Pirrung was caused to lose the consortium and society of his spouse Decedent Carole S. O'Neill-Pirrung.

TOLLING OF STATUTE OF LIMITATIONS

- 149. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
- 150. Decedent suffered an illness that had a latency period and did not arise until many years after exposure. Decedent was not aware at the time of her diagnosis that her ovarian cancer was caused by her use of the Defendants' Products. Consequently, the discovery rule applies to this case and the statute of limitations has been tolled until the day that Decedent knew or had reason to know that her ovarian cancer was linked to her use of Defendants' Products.
- 151. Furthermore, the running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and conduct. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Decedent the true risks associated with the Products.
- 152. As a result of Defendants' actions, Decedent and her prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.
- 153. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of the Products. Defendants were under a duty to disclose the true character, quality and nature of the Products because this was non-public information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the public, Decedent, Decedent's medical providers and/or health facilities.

154. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable product, notwithstanding the known or reasonably known risks. Plaintiff, Decedent, and Decedent's medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the abovereferenced claims and causes of action, and as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, emotional distress, fear of death, loss of enjoyment of life, loss of consortium and other non-economic damages in an amount to be determined at trial of this action;
- b. Awarding compensatory damages in excess of \$75,000 for Decedent's death in an amount to be determined at trial of this action;
- c. Awarding compensatory damages for Plaintiff's loss of love, support and companionship in an amount to be determined at trial of this action;
- d. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings, loss of inheritance, funeral, burial and related expenses and other economic damages in an amount to be determined at trial of his action;
- e. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Decedent in an amount sufficient to punish Defendants and deter future similar conduct;
- f. For an order requiring Defendants to immediately cease and desist from all fraudulent, deceptive, unlawful, and illegal conduct described above;
 - g. Pre-judgment interest;
 - h. Post-judgment interest;

Awarding Plaintiff's reasonable attorneys' fees; i. 1 j. Awarding Plaintiff the costs of these proceedings; and 2 Such other and further relief as this Court deems just and proper. k. 3 4 Dated: November 18, 2019 5 6 /s/ Michael J. Williams By: 7 Michael J. Williams, Esq. 8 Cellino & Barnes, PC 2500 Main Place Tower 9 350 Main Street Buffalo, NY 14202 10 Telephone: (800) 888-8888 Attorneys for Plaintiff 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 - 30 -COMPLAINT